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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,142	12/08/2000	Bernard Charles Sherman	PT-1877000	5119

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EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,142	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-11 are pending in the instant application. Acknowledgement is made of Applicant's Preliminary Amendment filed 12/7/2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sims (U.S. Pat. No. 5,288,507), further in view of Stuerzebecher (U.S. Pat. No. 5,523,321) and Kararli et al. (U.S. Pat. No. 5,935,939).

Sims relates to pharmaceutical compositions for use in the treatment of pain and Inflammation. The compositions can comprise an NSAID such as ibuprofen (col. 1, lines 51-53). The composition may further comprise an anti-ulcerative agent such as misoprostol (col. 4, lines 61-64). The composition may be administered in gelcaps, capsules, and tablets (col. 5, lines 1-3).

Kararli teaches that prostaglandins are relatively unstable and decompose above room temperature (col. 1, lines 33-38). For this reason, Kararli teaches stabilized amorphous dispersions of prostaglandins used in preparing pharmaceutical dosages. Misoprostol is suitable as a prostaglandin (col. 2, lines 9-38).

Stuerzebecher relates to combination products containing a prostaglandin, prostacyclin, or a prostacyclin analog, and an antagonist suitable for joint application (Abstract). It this treatment form, the amounts of prostaglandin and antagonist used are greatly reduced in comparison with the necessary dosages of the individual active substances.

In an example of a combination tablet made, Stuerzebecher teaches the granulation of several components, and molding into round tablets (see Example 1). Whereas Stuerzebecher does not term the granules that make up the composition "tablets", it is understood by the examiner that the granules are tablets of a specific size

Whereas Stuerzebecher does not term the granules that make up the composition "tablets", it is understood by the examiner that the granules are tablets of a specific size, and thus makes the use of "tablets" in the instant invention obvious. Motivation to utilize prostaglandin in combination with an NSAID such as ibuprofen would arisen in order to decrease the amount of prostaglandin and NSAID needed in comparison to taking the drugs separately. Furthermore, motivation to utilize a prostaglandin that has been dispersed in an excipient as taught by Kararli would have arisen in order to stabilize misoprostol used therein.

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franz et al. (U.S. Pat. No. 5,232,704) further in view of Stuerzebecher (U.S. Pat. No. 5,523,321).

Franz teaches a sustained release pharmaceutical dosage form comprised of a

capsule including bi-layer formulation. The bi-layer is made of a release layer and a buoyant layer. The release layer may consist of, for example, a NSAID such as diclofenac, piroxicam, ibuprofen, or naproxen, and misoprostol. Suitable amounts for the components can range from 25 to 75 milligrams for NSAID and 100-200 mm for misoprostol (col. 4, lines 4-10). In a specific embodiment, the ingredients are contained in clear hard gelatin capsules. Franz does not disclose that the NSAID and misoprostol used are tablets.

As stated above, Stuerzebecher teaches combination products containing a prostaglandin, prostacyclin, or a prostacyclin analog, and an antagonist suitable for joint application (Abstract). It is taught that the amounts of prostaglandin and antagonist used are greatly reduced in comparison with the necessary dosages of the individual active substances.

Whereas Stuerzebecher does not term the granules that make up the composition "tablets", it is understood by the examiner that the granules are tablets of a specific size, and thus make the use of "tablets" in the instant invention obvious. Motivation to make the bilayer of Franz in the form of Stuerzebecher would have arisen in order to greatly reduced the amounts of misoprostol and NSAID used, in comparison to the necessary dosages of the individual substances.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
February 25, 2002

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616